

Application No. 10/031,261  
Attorney Docket No. PG3694USW

### REMARKS / ARGUMENTS

Claims 13-32, 34-79, and 83-87 remain in this application. Claims 1, 29 and 29 have been amended for the reasons detained below.

#### A. CLAIMS ARE NOVEL OF EKENSTAM

Currently, Claims 1-5, 7, 8, 11-13, 15, 18-20, 29, 31, 32, 35-79, 84 and 87 are rejected as anticipated by US 2,889,958 to Ekenstam. Claim 1 has been amended to recite that the retainer is (i) *preformed*, (ii) *present in said first portion and suitable for receipt of product prior to being covered with said second portion*, and (iii) *present in said first portion and suitable for containment of a product after said retainer is exposed*.

In Ekenstam, the articles dispensed are packaged between protective layers forming a strip 9'. The Ekenstam pocket is created by the marginal edges of adjacent folds being fastened together, such as by adhesive. (Col 1, lines 14-16). The examiner has equated the "pocket" formed in Ekenstam by folding a single layer strip in accordion fashion, to the "retainer" of claim 1.

Applicant has amended claim 1 to emphasize the structural distinctness of the claim from Ekenstam pocket from the retainer claimed. The Ekenstam pocket is not "preformed" in the first portion, as called for in the claim 1. As the examiner has acknowledged, containment in the Ekenstam layers of the strip exists only as the result of sealing the marginal edges of the strip 9'. The examiner highlighted the "expanded bulging" portions of the first and second sheets as demonstrating the "pocket". Prior to folding the layer over and sealing the marginal edges of the portions of the layers to form the accordion strip, the article merely rests on top of the presumably flat layer of the strip. Thus, the "first portion" does not contain a "preformed" retainer as called for in claim 1. As Ekenstam lacks a "preformed retainer", the "retainer" is not "present in said first portion and suitable for receipt of product prior to be covered with said second portion", because of this, the contents to be held in the eventual pocket may shift causing filling problems. Further, the Ekenstam "pocket" would not be "present in the first portion and

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suitable for containment of a product after the retainer is exposed in use." This feature makes the retainer a suitable holder for holding the pocket contents prior to its removal. As Ekenstam lacks these features, Ekenstam does not anticipate claim 1.

In light of these amendments, applicant respectfully requests withdrawal of the 35 USC §102 rejection of claims 1-5, 7,8, 11-13, 15, 18-20, 32, 35-79, 84, and 87.

**B. AMENDED CLAIM 29 IS NOVEL AND NON-OBVIOUS OVER THE  
CITED PRIOR ART.**

Claim 29 has been amended to recite better recite the attributes of the retainer. Ekenstam does not disclose the step of forming a retainer as claimed. Prior to placing the article on the layer of the Ekenstam strip, there is no "retainer" in the layer which eventually forms the strip. The "bulging" of the pocket is formed only as a result of covering and sealing the Ekenstam strip 9'. Further, the layer in Ekenstam appears to revert to its flat form after the article has been ejected from the strip, as depicted in Figure 2 of that reference. In the absence of a formed retainer, there is no receptacle into which an article may be placed, and no receptacle from which material may be withdrawn after the retainer has been unsealed. The claimed method allows the formation of a retainer, which has utility after the retainer is uncovered during use. These features and method steps are not disclosed in Ekenstam, nor would such an approach be applicable to Ekenstam, as the retainer formed by the instant method would complicate or interfere ejection of the article from the Ekenstam dispenser, as well as potential jam the small space between the dispenser cover 2 and the guide 4.

For these reasons, method claim 29 is novel and non-obvious over Ekenstam. Claims 30 and 31 depend from claim 29 and are patentable for the reasons provided above.

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**C. CLAIMS ARE NON-OBVIOUS OVER EKENSTAM/KALLSTRÄND**

The Ekenstam reference relates to an article dispenser employing a strip containing a series of pockets formed by the folding of the strip in accordion fashion. One end of the strip is drawn out of the rectangular box dispenser, causing the pockets to be serially opened, and the contents of each pocket to be ejected from the dispenser from a slot in the dispenser. After opening the pocket, the flat strip material is drawn between a guide plate 4 and the dispenser cover 2, as in Figure 1.

US 5,660,169 to Kallstränd relates to a unit dose inhaler. The lower part of the inhaler has a depression 3 formed in it which contains a powder. The depression is covered by a separate tape, which hermetically seals the contents of the depression. Pulling the tape from the end protruding from the inhaler draws the tape over itself, peeling the portion of the tape that covers the depression away from the surface of the lower portion of the inhaler, exposing the depression contents. So exposed, the inhaler is placed in a condition that allows a patient to inhale the powder from the depression.

Kallstränd thus teaches using a separate tape to cover a depression, whereby removal of the tape allows the inhaler to be operated. Unlike Ekenstam, the material contained is not contained by the tape itself. Further, the tape does not transport articles within the device, as in Ekenstam. Further still, Kallstränd is directed at a one use device, whereas Ekenstam is directed at a multi-dispensing device.

Claim 6 is non-obvious over these references, as Ekenstam does not teach a preformed retainer, as discussed above. Kallstränd's use of plastic laminated foil does not remedy the shortcomings of Ekenstam in this regard. Further, one of ordinary skill would not be motivated to modify Ekenstam in such a way as to provide a strip with a feature that would contain an article after the strip is opened. The intent of Ekenstam is not to contain the article after opening, but to cause it to be ejected from the rectangular dispenser. Any feature which would inhibit this action would be disfavored. Further, in operating the Ekenstam, dispenser, the opened layers of the strip are drawn out of the

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dispenser between the guide and the cover, as shown in Figure 1. Likewise, any feature which would inhibit this action would be disfavored. Thus, as amended, the elements of Claim 6 are not disclosed in Ekenstam, and one would not be motivated to modify this reference based on the Kallstränd teachings of a depression, as its inclusion would negatively impact the functioning of the Ekenstam device both in ejecting articles and withdrawing "spent" layers of strip.

Claim 9 is also non-obvious. Ekenstam does not teach a preformed retainer, as discussed above, and it would not be appropriate to modify Ekenstam to include such a feature. Also, and contrary to comment of the examiner, the tape cover depicted in Kallstränd does not show a looped end. Fig. 1, #6 is directed to the tape. The tape is shown Fig. 1 has a fold where the tape folds back on itself as it is peeled away from the depression. This fold is not positioned at an "end" and is not a pull release tab. Figure 2, shows the end of the tape which is pulled by the user of the inhaler. The end of the tape shown in Figure 2 is flat and is not looped. For these multiple reasons, the claim is both novel and non-obvious.

Claims 16, 17, 21 and 22 are non-obvious. Again, Ekenstam does not teach a preformed retainer, and it would not be suitable to include such a feature. Therefore, no prima facie case of obviousness has been made out for these claims.

Claims 24 and 25 are non-obvious over Ekenstam/ Kallstränd. Both claims are ultimately dependent on claim 1, and are novel and non-obvious for the reason that Ekenstam does not teach nor is it suited to include a "preformed retainer", as previously discussed. Kallstränd's tubular inhaler housing has a body made up of an upper part and a lower part which are fused together. The lower part contains a depression 3 holding a powdered medicament. The tape 6 is not unitary with the body of the inhaler, is thinner and is narrower than the parts making up the tubular housing. The tape merely seals the depression until is ready to be accessed. Making unitary the tape and the lower body part of Kallstränd so as to form the carrier of claim 1, would not be desirable as due to the difference in physical dimensions of the tape and the lower body portion. Without this,

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no "carrier" as used in claim 1 exists. Further, if one did combine these elements to construct a carrier as in claim 1, there would not be any "holder for receipt of the retainer of the carrier" as claimed in claim 25. For these various reasons, claims 24 and 25 are both novel and non-obvious over Kallstr nd.

Claim 26, depends from claim 24, which depends from claim 21, which depends from claim 1. Claims 26 is both novel and non-obvious for the reasons provided in relation to claims 24 and 1.

Claims 27 and 28 recites a release mechanism which connects to the pull release tab of the carrier. First, claims 27 and 28 each depend from claim 26 and are novel and non-obvious for the reasons provide for claim 26 being patentable. In addition, the examiner indicates that a ridge provided in the upper portion of the tubular body is a release mechanism. Applicant believes that the examiner has failed to understand this aspect of the reference. As discussed at col. 4, line 66- col. 5, line 3, ridge 25 is aimed at directing air flow through the tubular housing when a patient inhales. It is in no way related to the operation of the tape 6. For this additional reason, claims 27 and 28 are novel and non-obvious.

Claims 85 and, indirectly, 86 depend from claim 21, which depends from claim 1. Claims 85 and 86 are novel and non-obvious for the reasons provided for claims 1 and 21.

For the reasons provided above, Applicant's requests withdrawal of the obviousness rejection of the claims over Ekenstam in light of Kallstr nd.

**D. CLAIMS ARE NON-OBVIOUS OVER EKENSTAM/KALLSTR ND AND JAHNSSON**

Jahns son is relied on for teaching particular inhaled medicines, as claimed in claims 23, 34 and 83. The combination of the references proposed by the examiner is inappropriate. First, the primary reference is unsuitable for delivering respiratory medicines, as the

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contents of each pocket is ejected from the dispenser as each pocket is opened. Therefore, one would not look to deliver respiratory powders with a dispenser described in Ekenstam, due to the difficulty in aerosolizing and delivering powdered inhaled medicaments. While these medicaments may be suitable for use in Kallstränd, the use of a preformed retainer would not be appropriate for adoption in a layer of the Ekenstam strip for the reasons already mentioned in this paper. Hence, although the various elements might be found in the references cited, only through the inappropriate use of hindsight can they be combined to construct the claimed invention. As such, applicant's assert that this combination of references is improper.

Turning now to the particular rejections, Claim 23 is dependent on claim 21, which depends from claim 1. Claim 23 is novel and non-obvious over the references relied on by the examiner for the reasons provided above for the patentability for claims 1 and 21.

Claim 34 was amended to depend on claim 86, which depends from claim 85, which depends from claim 21, which depends from claim 1. Claims 34 is novel and non-obvious for the reasons provided for claims 1 and 21, 85 and 86 above.

Claim 83 has been amended to dependant from claim 21, which depends from claim 1. Claim 83 is novel and non-obvious over the references relied on by the examiner for the reasons provided above for the patentability for claims 1 and 21.

For the reasons provided above, Applicant's requests withdrawal of the obviousness rejection of the claims over Ekenstam in light of Kallstränd and Jahnsson.

**E. CLAIMS ARE NON-OBVIOUS OVER EKENSTAM / LEVINE**

Claims 10 and 14 have been rejected over Ekenstam (US 2,889,958) in view of Levine (US 4,884,719). Neither Ekenstam nor Levine teach or suggest a preformed retainer in a first portion of a carrier strip. No prima facie case of obviousness has been established.

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For the reasons provided above, Applicant's requests withdrawal of the obviousness rejection of the claims over Ekenstam in light of Levine.

**F. CLAIM OBJECTION IS BASED ON A MISUNDERSTANDING OF THE CLAIM LANGUAGE**

Claim 84 recites a "join." The claim is correct as the "join" joins the base portion to the first portion defining the preformed retainer below the preformed retainer. Note that the term join is also used in similar fashion in claim 1 and 29. As the claim is not ambiguous or erroneous, and withdrawal of the objection is requested.

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### CONCLUSION

In light of these amendments, all issued raised by the examiner to date have been addressed. As such, the claims, as amended, are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,

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